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Original Article

Advancing Gastrointestinal Disorders Treatment in Poorly Managed Patients Resistant to Conventional Therapies

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Abstract

Background and objectives: Conventional PPIs are first-line treatment for acid-related diseases but have limitations such as slow onset, P450 polymorphism interactions, inadequate night-time effects, and instability in acidic conditions. Therefore, potassium-competitive acid blockers (P-CABs) such as vonoprazan, were developed to address these issues, offering rapid, long-lasting, and reversible inhibition of the gastric proton pump. We conducted a nationwide survey to assess opinions and prescribing tendencies of healthcare professionals regarding the efficacy, safety, and clinical application of vonoprazan as an alternative to PPIs, in the management of gastrointestinal disorders.

Methods: A questionnaire was circulated to healthcare professionals (N=88) across PAN India. All the healthcare professionals completed the survey and responses were captured and analysed.

Results: The present questionnaire-based survey assessed the opinions of healthcare professionals in terms of efficacy, safety and tolerability of vonoprazan as an alternative to PPI for the treatment of GERD, erosive esophagitis (EE), gastric and duodenal ulcers, prevention of recurrence of NSAID induced ulcers and management of *H pylori* infection. The results show a strong preference among healthcare professionals for vonoprazan, with 85.2% supporting its use in managing GERD symptoms and EE, 93% favour vonoprazan 20 mg for improving EE healing rates, 93.2% found it effective and superior versus PPI in treatment of recurrent gastric and duodenal ulcer, 73.9% prefer it for the treatment regimen for *H. pylori* eradication, 75% reported to switch to vonoprazan for its rapid action and 66.7% regard it as a safe and effective alternative to PPIs. Additionally, all healthcare professionals (100%) were willing to prescribe it for managing nocturnal acid breakthroughs.

Conclusions: Vonoprazan is an effective, safe, well-tolerated, and reliable alternative to PPIs for patients with GERD, EE, gastric and duodenal ulcers as well as for prevention of recurrence of NSAID induced-ulcers and management of *H pylori* infection.

Key words: Gastrointestinal disorders, Gastroesophageal reflux disease symptoms, Proton-pump inhibitor, Vonoprazan

INTRODUCTION

Acid-suppressive agents are commonly used to treat various gastrointestinal (GI) disorders,[1] including gastroesophageal reflux disease (GERD), a prevalent condition marked by heartburn and acid regurgitation due to stomach contents refluxing into the esophagus. GERD significantly impacts patients' quality of life and imposes a considerable burden on health-care systems.[2] Proton-pump inhibitors (PPIs) have long been the conventional treatment for acid-related disorders, including GERD, erosive esophagitis (EO),[3] gastric and duodenal ulcers, and *Helicobacter pylori* eradication.[4] However, PPIs often fall short in providing optimal acid suppression, with issues such as delayed onset of action, variability in effectiveness due to cytochrome P450 polymorphisms, inadequate symptom relief at night, and instability in acidic environments. Despite advancements in modified PPI formulations, these treatments have only marginally improved outcomes. In light of these limitations, vonoprazan has emerged as an effective, safe, and well-tolerated alternative to PPIs. It offers reliable acid suppression, helping manage EO,

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prevent non-steroidal anti-inflammatory drug (NSAID)-induced ulcer recurrence, and treat *H. pylori* infections, thereby providing a promising solution for patients with upper GI disorders.[2,4,5]

Vonoprazan, a potassium-competitive acid blocker, has emerged as a promising alternative, offering rapid, sustained and reversible inhibition of the gastric hydrogen-potassium ATPase (the proton pump), with considerable advantages over traditional PPIs[2,5] vonoprazan exerts its therapeutic action by inhibiting the H^+, K^+-ATPase enzyme, thereby disrupting the final step in the gastric acid secretion process within parietal cells. Notably, it acts swiftly and does not rely on acid-induced activation to manifest its therapeutic effect [Figure 1].[6,7] Vonoprazan is preferentially accumulated in parietal cells, irrespective of acidic or neutral conditions. Unlike other agents, it does not necessitate an acidic milieu for activation, maintaining long-lasting stability at its site of action, while demonstrating commendable safety and tolerability.[2]

Vonoprazan, indicated for the treatment of gastric and duodenal ulcers, EO and prevention of low-dose aspirin (LDA) or NSAID-related gastric and duodenal ulcer recurrence, emerges as a notable advancement over traditional PPIs [Table 1 and Figure 2],[2] with its rapid onset of action, enduring acid suppression and remarkable consistency in acid suppression across the population. Moreover, it remains largely unaffected by dietary factors. These compelling advantages have been robustly validated in clinical trials, paving the way for its approval in the treatment of several acid-related ailments.[8]

METHODS

A questionnaire related to gaps in the management of GI disorders with PPIs and the use of vonoprazan as an alternative was circulated to health-care professionals (HCPs) across pan-India. In total, 88 HCPs participated in the survey. Among the HCPs surveyed, 85 were gastroenterologists (96%), three were consulting physicians (3%), and one was a hematologist (1%). All the HCPs completed the survey, and their responses were captured and analyzed. Responses to the survey questions were documented in Microsoft Excel, and the average was calculated to determine the percentage of HCPs favoring each answer.

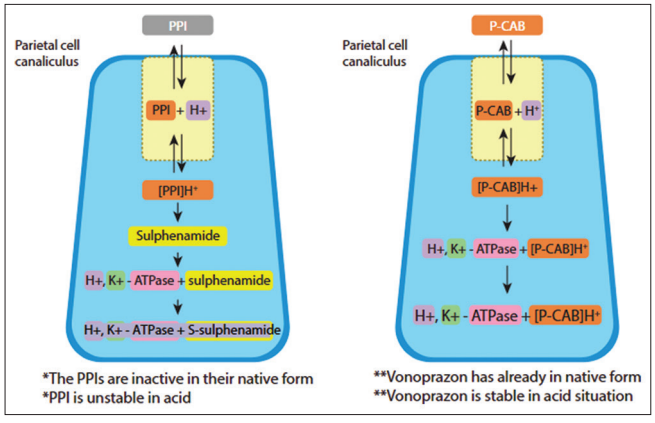

Figure 1: The mode of action of vonoprazan and proton-pump inhibitors against *Helicobacter pylori* infection

Expert Opinions

The responses of the HCPs for each question have been described in the following text:

Opinions on the onset of action of PPIs in achieving maximum acid suppression and symptom relief

Most of the HCPs (72.7%) agreed to the fact that PPIs have a slow, cumulative onset, requiring multiple doses over several days for full therapeutic effect in treating GERD, around 15.9% noted the gradual onset, 9.1% emphasised the need for multiple doses for maximum acid suppression and 2.3% mentioned that several doses are needed for symptom relief.

Role of Vonoprazan in Addressing Unmet Needs in GERD and EO Management

The majority of HCPs (85.2%) agreed with vonoprazan's use in clinical practice for addressing unmet needs in managing GERD and EO; on the contrary, 13.6% partially agreed and only 1.1% showed disagreement, suggesting strong support for the use of vonoprazan as an advanced treatment option in the clinical management of GERD [Figure 3].

Table 1. Comparison of Potassium-competitive Acid Blocker (P-CAB) and Proton Pump Inhibitor (PPI)

P-CAB (Vonoprazan)		PPI
Maximal acid suppression after dosing (day)	1	3-5
Influence of CYP2C19 polymorphisms	-	+
Influence of meal stability in acidic conditions	-	+
Acid suppression at night (pH 4 HTR) (mean + SD, %)	> 67.9 ± 28.3 VS 84.3 + 2.03 VS 12.9 + 10.9 (E) 15.3 + 13.3 (R)	
H. pylori eradication rate (first-line triple therapy) (%)	92.6	75.9 (L)
Healing rate of server reflux esophagitis (LA, grade C/D) (%) PPI-refractory GERD	88.0-96.0 >	53.9-82.6 (L)

Preference for prescribing vonoprazan 20 mg over PPIs for improved EO healing rates at 8 weeks

- A substantial majority (95.5%) of HCPs chose vonoprazan 20 mg for the management of EO. Only 1.1% of the participating doctors favored its use for high-grade esophageal lesions, whereas others were interested in further research or opted not to prescribe it.

Vonoprazan in the eradication of H. pylori infection

- The majority of HCPs (73%: Strongly recommend; 26.1%: Recommend) indicated they are likely to prefer a vonoprazan-based treatment regimen for *H. pylori* eradication.

Vonoprazan superiority over PPIs

- Around 71 HCPs (80.7%) agreed that vonoprazan demonstrates superior and more consistent acid suppression than PPIs, resulting in rapid and sustained symptom relief and mucosal healing, whereas 15 HCPs (17.0%) partially agreed, and two of them (2.3%) somewhat agreed.
- 65.9% of HCPs strongly agreed that vonoprazan is safe and effective and has shown promising results as a replacement for PPIs, whereas seven HCPs (8.0%) somewhat agreed, 22 HCPs (25.0%) partially agreed, and only one of them (1.1%) disagreed [Figure 4]
- All the HCPs expressed their inclination toward prescribing vonoprazan for managing GERD symptoms in patients resistant to PPIs
- All the HCPs (100%, $n = 88$) expressed their willingness to prescribe vonoprazan for better management of nocturnal acid breakthroughs
- All 88 HCPs (100%) would consider switching to vonoprazan for better patient compliance, its convenience, and effectiveness in GERD treatment
- Around 93.2% HCPs agreed on the superior efficacy of vonoprazan when compared to PPIs in patients with recurrent gastric and duodenal ulcers, whereas 3.4% disagreed, 1.1% partially agreed, and only two HCPs (2.3%) suggested the need for further research to validate it.

Vonoprazan use in achieving and maintaining healing of mucosal breaks in patients with GERD and in treating PPI-resistant GERD

- Around 93.2% of HCPs preferred vonoprazan-based therapies for patients with GERD and PPI-resistant GERD, highlighting a strong preference for vonoprazan as a treatment option, whereas 6.8% indicated that they would not suggest it.

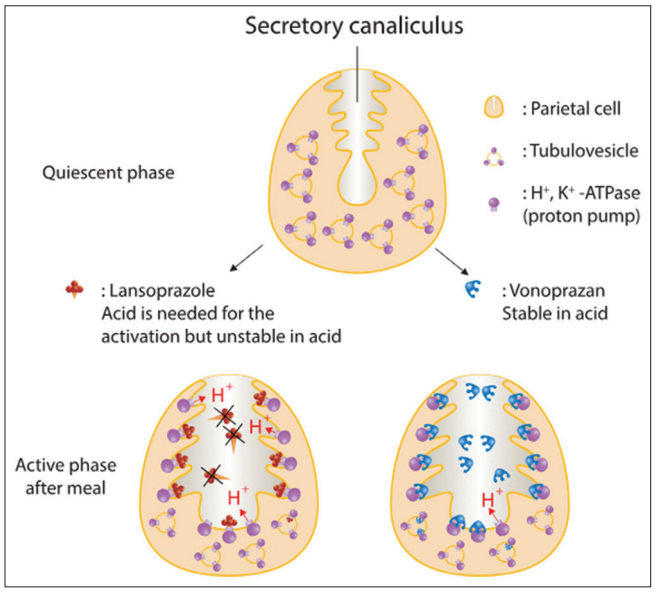

Figure 2: Comparison of mechanisms of action of lansoprazole (conventional proton-pump inhibitor) and vonoprazan (potassium-competitive acid blocker)

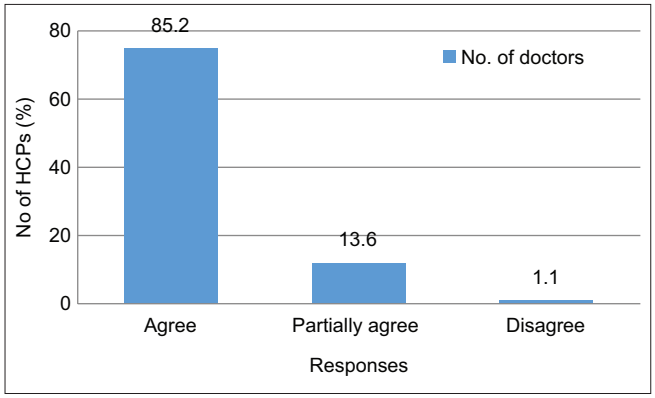

Figure 3: Recommendation of vonoprazan for gastroesophageal reflux disease management

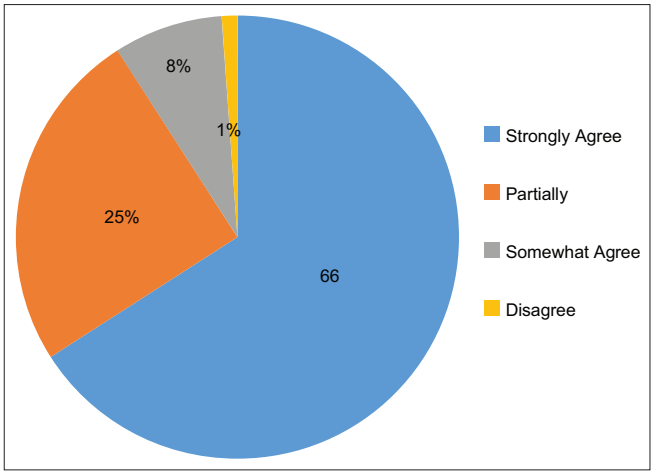

Figure 4: Vonoprazan safety and efficacy as an alternative to proton-pump inhibitors for gastroesophageal reflux disease management

Maximal acid suppression of vonoprazan versus PPIs

- Approximately 75% of HCPs are very likely to prescribe vonoprazan as an alternative to PPIs, whereas 25% are somewhat likely to make the switch, highlighting a greater preference for incorporating vonoprazan into the treatment regimen due to its rapid action and superior efficacy compared to traditional PPIs.

Effectiveness of vonoprazan in treating acid reflux (GERD), peptic ulcer disease, and H. pylori infection

- As many as 75% of HCPs are highly likely to recommend vonoprazan in their clinical practice, whereas the remaining 25% are moderately likely to recommend it, reflecting strong confidence in vonoprazan's clinical benefits.

Opinion on prescribing vonoprazan as dual and triple therapy regimens for H. pylori infection

- Around 82.64% of HCPs (56%: Strongly recommend; 40.9%: Recommend) favored recommending dual and triple vonoprazan-based therapy in clinical settings, whereas only two participants (1.76%) chose not to recommend these regimens, suggesting broader support for vonoprazan-based therapy in clinical practice [Figure 5].

Preference for prescribing vonoprazan in clinical practice for H. pylori eradication therapy

- The survey results suggested that 66 HCPs (76.7%) are very likely to prescribe vonoprazan for patients undergoing *H. pylori* eradication therapy, with 20 HCPs (23.5%) somewhat likely to prescribe it, whereas only two HCPs (2.3%) are unlikely to do so, demonstrating a greater support for vonoprazan as an effective treatment option for *H. pylori* eradication [Figure 6].

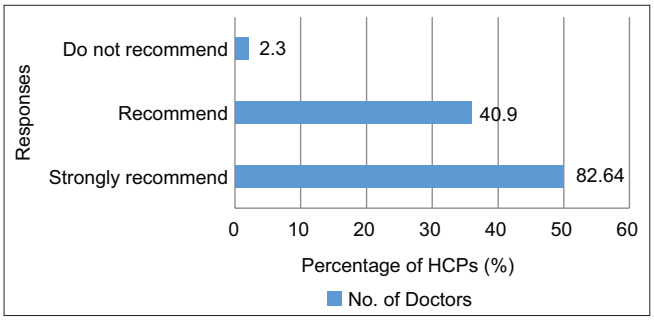

Figure 5: Vonoprazan recommendations for implementing vonoprazan-based therapy regimens in clinical practice

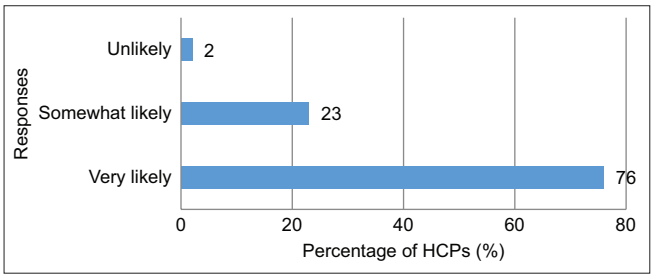

Figure 6: Recommendations for prescribing vonoprazan for *Helicobacter pylori* therapy

Vonoprazan in the Management of Acid-Related Disorders

Pharmacodynamic properties of vonoprazan

Vonoprazan exhibits a rapid onset and sustained acid suppression (both day-time and night-time acid secretion)[4] with its pharmacokinetics largely unaffected by CYP2C19 polymorphisms and food-related impact. It reaches peak plasma concentrations within 1–3 h post-dose and has dose-proportional exposure in the dose range of 10–40 mg, with steady-state concentrations achieved by day 3–4. In twice-daily dosing, plasma exposure is 1.8 times higher compared to steady state. Vonoprazan binds H^+/K^+-ATPase with high affinity, both in active and inactive states, with acid suppression being dose-dependent in patients who received vonoprazan 10–40 mg optical density for 7 days, as demonstrated in randomized clinical trials.[5]

Therapeutic efficacy and safety of vonoprazan

The vonoprazan-based dual and triple therapy regimens were generally well tolerated in PHALCON-HP. In these patients, *H. pylori* eradication rates with vonoprazan dual therapy, vonoprazan triple therapy, and lansoprazole triple therapy, respectively, were 78.5%, 84.7%, and 78.8%. In addition, vonoprazan has advantages, including a rapid onset of action and no effect on food intake, making vonoprazan-based dual and triple therapy regimens valuable alternatives to standard PPI-based triple therapy in the treatment of *H. pylori* infection.[5] In a follow-up study by Tanabe *et al.*, 93.8% of patients with PPI-resistant reflux esophagitis maintained endoscopic remission after 52 weeks of vonoprazan 10 mg maintenance therapy, and concluded that long-term maintenance with vonoprazan 10 mg is effective for sustaining healing in PPI-resistant reflux esophagitis patients.[9]

Several studies have also presented safety evidence supporting the use of vonoprazan in the management of GERD. A meta-analysis of 77 studies showed no significant differences in adverse events (AEs) between vonoprazan and PPIs, with incidences of 20%, 7%, 1% and 1% for any AEs, drug-related AEs, serious AEs, and AEs leading to discontinuation, respectively. The study concluded that vonoprazan is well tolerated and has similar safety to PPIs.[1]

The study by Xu *et al.* evaluating the incidence and type of AE associated with vonoprazan reported it to be well

tolerated in patients with GI disorders.[1] Similarly, Yang *et al.* in their study highlighted vonoprazan as clinically safe and well-tolerated. Vonoprazan is found to be tolerable with the simultaneous use of antibiotics. When used in combination with amoxicillin, with or without clarithromycin, vonoprazan is generally well tolerated in adults with *H. pylori* infection.[4,5] In the PHALCON-HP trial, treatment-emergent AEs were reported in 29.9%, 34.1%, and 34.5% of patients in the vonoprazan dual therapy, vonoprazan triple therapy, and lansoprazole triple therapy groups, respectively. In all groups, most TEAEs were mild-to-moderate in severity.[5]

Vonoprazan in different clinical indications

Management of GERD resistant to PPI

PPIs are first-line treatments for GERD and non-erosive reflux disease (NERD), but a subset of GERD patients, particularly those with NERD, shows poor response to PPI therapy. Although various medical, surgical, and endoscopic options have been explored for NERD, none are currently recommended beyond PPIs. Although altering PPI type or adding other drugs has been suggested, evidence remains limited. Thus, an effective alternative pharmacological treatment is urgently needed.[10] In a study by Niikura *et al.*, 69.2% of patients with severe GERD ($n = 26$) with no endoscopic mucosal breaks experienced improvement after switching from PPI to vonoprazan ($n = 15$) 57.7% received 20 mg/day; $n = 11$ (42.3%) received 10 mg/day for 12 weeks. This change was strongly linked to symptom improvement ($P < 0.001$), with a significant reduction in GERD-Q scores (from 11.96 to 8.92, $P < 0.001$). Thus, this suggests that vonoprazan emerges as a promising option for PPI-resistant GERD.[10]

In a randomized trial by Fass *et al.* (2023), patients with NERD were assigned to 10 mg, 20 mg, 40 mg vonoprazan, or placebo for 6 weeks. Complete relief of heartburn episodes was seen in 56.0%, 60.6%, and 70.0% of the vonoprazan groups, respectively, compared to 27.3% in the placebo group ($P < 0.0001$). Vonoprazan provided significantly more relief than the placebo 1 h post-dose.[11] The follow-up study by Tanabe *et al.* demonstrated that vonoprazan 20 mg is effective in healing 87.5% of patients with PPI-resistant reflux esophagitis and endoscopic remission.[9] These evidences, in addition to the survey insights, suggest vonoprazan as a reliable treatment option for the management of patients with GERD resistant to PPI.j1

Management of EO

Clinical studies on vonoprazan 20 mg were found to be effective and non-inferior to lansoprazole 30 mg in achieving endoscopic EO healing at 8 weeks (vonoprazan: 92.4%; lansoprazole: 91.3%), with slightly higher healing rates at 2 (vonoprazan: 75%; lansoprazole: 67%) and 4 (vonoprazan: 85.3%; lansoprazole: 83.5%) weeks. The safety profile of vonoprazan was similar to that of lansoprazole 30 mg, showing comparable outcomes in the patient populations. In a phase III, double-blind, multicentre study, patients with endoscopically confirmed EO were randomized 1:1 to receive either vonoprazan 20 mg or lansoprazole 30 mg OD for up to 8 weeks. The vonoprazan group ($n = 238$) achieved an 8-week EO healing rate of 92.4%, whereas the lansoprazole group ($n = 230$) had a rate of 91.3% (a difference of 1.1%, 95% CI: –3.822–6.087%). Overall, vonoprazan showed slightly higher EO healing rates compared to lansoprazole, with comparable safety outcomes between both treatment arms.[3]

One of the randomised clinical trial conducted in 2016, investigated the efficacy of vonoprazan on esophageal mucosal healing and reported that 99% of patients with EO had mucosal healing after 8 weeks of vonoprazan therapy.[10] These findings, along with the survey results showing that 85.2% of HCPs preferring vonoprazan to address the unmet needs in managing EO, highlight the positive role vonoprazan plays in EO treatment.

Management of *H. pylori* Infection

Studies show that vonoprazan-based regimens outperform PPI-based triple therapy, suggesting that its stronger acid suppression enhances the efficacy of antibiotics for *H. pylori* eradication.[5] In a systematic review and meta-analysis of five studies by Zhang *et al.*, the cure rates of 1,852 patients analyzed in the study for vonoprazan/amoxicillin dual therapy were 85.6%. In addition, vonoprazan/amoxicillin dual therapy showed significant superiority over omeprazole or lansoprazole-based triple therapy ($P = 0.001$).[12]

Another randomized, double-blind study showed that vonoprazan at 20 mg achieved a 92.6% eradication rate for *H. pylori*, outperforming lansoprazole 30 mg at 75.9%. Both treatments were effective, proving vonoprazan's non-inferiority [Table 1]. Yet another meta-analysis demonstrated the superiority of vonoprazan-based triple therapy over conventional PPI-based regimens, suggesting that vonoprazan should be the first-line treatment for *H. pylori* eradication.[2] These findings align with the survey results, where 73.9% of HCPs indicated a strong preference for vonoprazan in their *H. pylori* treatment regimen.

Treatment of gastric and duodenal ulcers

Although PPIs are effective and generally well tolerated, clinical trials show that ulcer recurrence still occurs in some patients, highlighting the need for alternative treatments.[6] A systematic review by Moraes-Filho *et al.* assessed the safety of Vonoprazan in managing GERD, esophagitis, gastric/peptic ulcers, and NSAID-induced ulcers. The study found

vonoprazan to have a favorable safety profile, especially compared to PPIs such as lansoprazole, making it a promising and safe therapeutic option for the treatment of ulcers.

As per study by Moraes-Filho JP, *et al.* (2022), no significant difference in efficacy, safety, or AEs between vonoprazan and PPIs was found for treating peptic ulcers after endoscopic submucosal dissection (RR = 0.65; 95% CI: 0.31–1.38).[13] Oshima and Miwa, in their review article, shared that randomized controlled trials confirmed the non-inferiority of vonoprazan in an 8-week treatment of gastric ulcers, with healing rates of 93.5% for vonoprazan and 93.8% for lansoprazole.[2]

Prevention of recurrence of LDA/NSAID-related ulcers

For adults who cannot discontinue NSAIDs, PPIs remain the standard approach to prevent NSAID-induced peptic ulcer recurrence. Although PPIs are generally well tolerated and effective, clinical trials reveal that ulcer recurrence persists in some patients, necessitating alternative treatments.[6] Vonoprazan, which offers rapid acid suppression from the outset, shows no significant interaction with NSAIDs and is well-tolerated. The clinical trials confirmed that vonoprazan (10 mg and 20 mg) effectively prevents NSAID-related GI ulcers, aligning with PPI prevention outcomes.[2] In a phase III study evaluating vonoprazan's efficacy in preventing recurrent upper GI ulcers in patients undergoing prolonged LDA therapy, the recurrence rate was 2.8% after 24 weeks of LDA. With lansoprazole 15 mg or vonoprazan 10 mg, the recurrence dropped to 0.5%. Thus, vonoprazan 10 mg proves equally effective as lansoprazole 15 mg in preventing such LDA/NSAID-induced ulcers.[2]

CONCLUSION

A significant body of research has established that vonoprazan surpasses PPIs in the treatment of GI disorders. In parallel, the survey reveals that the majority of HCPs prefer vonoprazan over PPIs. As a result, vonoprazan stands out as a promising and effective antisecretory agent, offering a viable treatment option for patients with GI disorders that are resistant to or poorly controlled by PPI therapy.

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